DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 28, 2014

Specialty Surgical Products Incorporated
Ms. Sherry Null
Vice President, Regulatory Affairs
1123 North U.S. Highway 93
Victor, Montana 59875

Re: K140383
Trade/Device Name: AlloX2 Tissue Expanders
Regulatory Class: Unclassified
Product Code: LJC
Dated: September 30, 2014
Received: October 1, 2014

Dear Ms. Null:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140383

Device Name
AlloX2 Tissue Expanders

Indications for Use *(Describe)*
AlloX2 Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities.

Additionally, the AlloX2 Tissue Expanders contain a silicone drain component which allows access to and drainage of latent fluids from the periprosthetic space. This drain component does not replace short-term, immediate, intraoperatively placed drains.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

510(k) Notification K140383

GENERAL INFORMATION

Applicant:
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1123 North U.S. Highway 93
Victor, MT 59875
U.S.A.
Phone: 406-961-0102
Fax: 406-961-0103

Contact Person:
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Vice President, Regulatory Affairs
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U.S.A.
Phone: 406-961-0102
Fax: 406-961-0103
Email: snull@ssp-inc.com

Date Prepared: October 23, 2014

Classification:
Unclassified (pre-amendment)

Product Code:
LCJ

Trade Name:
$AlloX_2$ Tissue Expanders

Generic/Common Name:
Expander, skin, inflatable

Primary Predicate Device
Silicone Tissue Expanders (K070303)

Additional Predicate Device
Heyer Schulte (Jackson-Pratt) Closed Wound Drain (K801766)

Indications for Use
$AlloX_2$ Tissue Expanders are intended for temporary (less than six month) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid treatment of soft tissue deformities.

Additionally, the AlloX2 Tissue Expanders contain a silicone drain component which allows access to and drainage of fluids from the periprosthetic space. This drain component does not replace short-term, immediate, intraoperatively placed drains.

510(k) SUMMARY (CONT.)

The $AlloX_2$ Tissue Expander configurations are substantially equivalent in material, function, performance and design to the Silicone Tissue Expanders marketed by Specialty Surgical Products cleared via 510(k) submission K070303. The AlloX2 configurations are substantially equivalent in material, function and performance to the Heyer Schulte (Jackson-Pratt) Closed Wound Drains cleared via 510(k) submission K801766.

Relevant testing was performed in accordance with ASTM F1441-03 "Standard Specification for Soft-Tissue Expander Devices." The following table lists bench testing performed and the results for each test.

Testing Type	Test Description	Results
Testing in accordance with ASTM F1441-03	Tube Shell Junction	The $AlloX_2$ passed all testing and met all product specification requirements.
	Injection/Drain Port Competence	
	Overexpansion	
	Tubing Length Adapter Strength	
	Critical Fused Joint	
Functional Testing	Adhered Joint	The $AlloX_2$ passed all functional testing and met all product specification requirements.
	Drain System	
	Magnetic Detection	

The collective results of the performance testing demonstrates that the $AlloX_2$ meets all established product specification requirements and does not raise any new questions of safety or effectiveness as compared to the predicate device.

Product Description

The $AlloX_2$ Tissue Expanders are constructed as a unit from silicone elastomer and consist of a smooth or textured expansion envelope with an integral magnetic injection port. Specialty Surgical Products is proposing that an integral or remote (connected by tubing) drain port be integrated into the predicate device to facilitate the drainage of fluid in the periprosthetic pocket. The port design and magnetic technology/concept are the same as those of the predicate injection ports. The principles of operation of the subject device methodology are identical to that of the primary predicate Silicone Tissue Expander and the additional predicate Closed Wound Drain.

The proposed $AlloX_2$ Tissue Expanders will have the same indications for use as the primary predicate device, the Silicone Tissue Expander (K070303) and the same intended use as the additional predicate Closed Wound Drain (K801766).

Substantial Equivalence

The $AlloX_2$ Tissue Expanders are substantially equivalent to the predicate devices with regard to function, intended use and technological characteristics. Any differences in the technological characteristics between the devices do not raise any new issues of safety or

510(k) SUMMARY (CONT.)

efficacy. Thus, the proposed AlloX_2 Tissue Expanders are substantially equivalent to the predicate devices.

Conclusion

The proposed AlloX_2 Tissue Expanders have the same technological characteristics as the predicate devices. The differences in design do not change the indications for use/intended use for the primary predicate SSP Silicone Tissue Expander #K070303 and do no change the intended use of the additional predicate Heyer Schulte (Jackson-Pratt) Closed Wound Drain (K801766) or raise any new issues of safety or effectiveness as compared to the predicates.

Summary

The AlloX_2 Tissue Expanders are substantially equivalent to the predicate devices.